



Atty Dkt. No. 2300-0999
Client Dkt. No. 0999.003
PATENT

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In Re Application of:

David B. RING

Serial No.: 08/349,489

Art Unit: 1642

Filing Date: December 2, 1994

Examiner: Y. Eyster

Title: METHOD OF PROMOTING AN
IMMUNE RESPONSE WITH A
BISPECIFIC ANTIBODY

21
169
1-500

In re KATZ DECLARATION

I, David B. Ring, declare as follows:

1. I am the sole inventor of the subject matter disclosed and claimed in the above-referenced patent application, U.S. Serial No. 08/349,489.

2. I am a co-author of Weiner et al. (1994) *Proc. Am. Assoc. Cancer Res.* 35:219 (Abstract #1309) and Weiner et al. (1994) *Proc. Assoc. Clin. Oncology* 13:800 (Abstract #978).

3. The non-inventor co-authors on the publications cited in paragraph 2, L.M. Weiner, W. Li, I.E. Palazzo, M. Davey, V Rivera and R.K. Alpaugh, did not conceive of the subject matter claimed in the above-identified patent application. Specifically, these non-inventor co-authors were involved in carrying out and evaluating studies of the bispecific antibody 2B1 in eleven patients with c-erbB-2(+) tumors. Dr. Louis M. Weiner was Chairman of Medical Oncology at Fox Chase Cancer Center and supervised Phase I clinical trials of 2B1 aimed at evaluating the safety of bispecific antibody 2B1. R. K. Alpaugh, I. E. Garcia de Palazzo and W. Li worked in Dr. Weiner's laboratory. M. Davey and V. Rivera were clinical research coordinators on the 2B1 clinical trials that I

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had instructed be performed. At my direction, the non-inventor co-authors also collected patient plasma samples for the analysis of possible induction of antibody responses to tumor antigens. Thus, Weiner, Li, Palazzo, Davey, Rivera and Alpaugh did not conceive of the claimed invention and any work they performed related to this invention was performed at my direction.

4. I am also a co-author of the following articles: Hsieh-Ma et al (1992) *Cancer Res.* 52:6832-6839; Weiner et al. (1993) *Cancer Res.* 53:94-100 and Ring et al. (1991) in *Breast Epithelial Antigens*, pp. 99-104.

5. The non-inventor co-authors on the publications cited in paragraph 4, S. Hsieh-Ma, A. Eaton, T. Shi, J. Reeder, J. Flatgaard, L.M. Weiner, M. Holmes, G. Adams, F. LaCreta, P. Watts and I. Garcia de Palazzo, did not conceive of the subject matter claimed in the above-identified patent application. The Hsieh-Ma et al. and Ring et al. publications did not involve use of 2B1 in human patients, and none of the publications demonstrate that 2B1 therapy can induce patient antibody responses. Furthermore, any work performed by all of the non-inventor co-authors of these three publications which relates to the claimed invention was performed at my direction. In particular, S. Hsieh-Ma and A. Eaton performed cytotoxicity experiments, T. Shi worked on cell sorter experiments, and J. Reeder and J. Flatgaard were involved in antibody purification and fragment generation. L.M. Weiner supervised experiments involving animal models. M. Holmes, G. Adams, F. LaCreta, P. Watts and I. Garcia de Palazzo worked with Dr. Weiner to carry out these experiments. Thus, none of these co-authors conceived of the claimed invention and none of the work they performed was concerned with the induction of host antibody responses to tumor antigens.

6. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of

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PATENT

the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Date: x DEC. 16, 1999

Signature: x

David B. Ring

David B. Ring



American Type Culture Collection

12301 Parklawn Drive • Rockville, MD 20852 USA • Telephone: (301)231-5520 Telex: 898-055 ATCCNORTH • FAX: 301-770-2587

BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF
THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

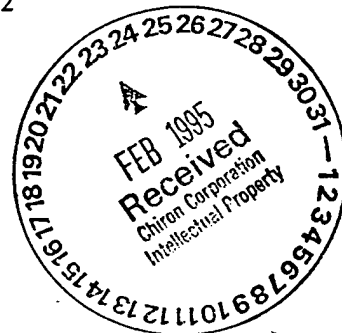
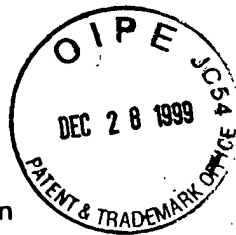
INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

COPY

To: (Name and Address of Depositor or Attorney)

Chiron Corporation
Attn: Karen Van Note
4560 Horton Street
Emeryville, CA 94608-2916



Deposited on Behalf of: Chiron Corporation

Identification Reference by Depositor:

ATCC Designation

42H8cl, CMCC #11216

HB-11830

The deposit was accompanied by: ☐ a scientific description ☐ a proposed taxonomic description indicated above.

The deposit was received February 7, 1995 by this International Depository Authority and has been accepted.

AT YOUR REQUEST:

☒ We will inform you of requests for the strain for 30 years.

The strain will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strain and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strain.

If the culture should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace it with living culture of the same.

The strain will be maintained for a period of at least 30 years after the date of deposit, and for a period of at least five years after the most recent request for a sample. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the culture cited above was tested February 10, 1995. On that date, the culture was viable.

International Depository Authority: American Type Culture Collection, Rockville, Md. 20852 USA

Signature of person having authority to represent ATCC:

Annette L. Bade, Director, Patent Depository

Date: February 15, 1995

cc: Leigh Firestone

994.001



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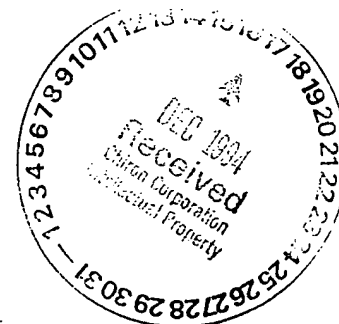
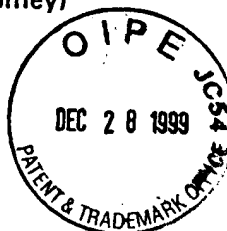
BUDAPEST TREATY ON THE INTERNATIONAL RECOGNITION OF THE DEPOSIT OF MICROORGANISMS FOR THE PURPOSES OF PATENT PROCEDURE

INTERNATIONAL FORM

RECEIPT IN THE CASE OF AN ORIGINAL DEPOSIT ISSUED PURSUANT TO RULE 7.3
AND VIABILITY STATEMENT ISSUED PURSUANT TO RULE 10.2

To: (Name and Address of Depositor or Attorney)

Chiron Corporation
Attention: Karen Van Note
4560 Horton Street
Emeryville, CA 94608-2916



Deposited on Behalf of: Chiron Corporation

Identification Reference by Depositor:

ATCC Designation

Hybridoma 36H3, CMCC #11215
Hybridoma 35E6, CMCC #11218

HB 11768
HB 11769

The deposits were accompanied by: ☐ a scientific description ☐ a proposed taxonomic description indicated above.

The deposits were received December 6, 1994 by this International Depository Authority and have been accepted.

AT YOUR REQUEST:

☒ We will inform you of requests for the strains for 30 years.

The strains will be made available if a patent office signatory to the Budapest Treaty certifies one's right to receive, or if a U.S. Patent is issued citing the strains and ATCC is instructed by the United States Patent & Trademark Office or the depositor to release said strain.

If the cultures should die or be destroyed during the effective term of the deposit, it shall be your responsibility to replace them with living cultures of the same.

The strains will be maintained for a period of at least 30 years after the date of deposit, and for a period of at least five years after the most recent request for a sample. The United States and many other countries are signatory to the Budapest Treaty.

The viability of the cultures cited above was tested December 8, 1994. On that date, the cultures were viable.

International Depository Authority: American Type Culture Collection, Rockville, Md. 20852 USA

Signature of person having authority to represent ATCC:

Annette L. Bade, Director, Patent Depository

Date: December 8, 1994

cc: Leigh Firestone